IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Edith SORENSEN	**Confirmation No. : 3993** Group Art Unit: 1611
Appln. No.	: 10/582,079 (National Stage of International Application No. PCT/EP2004/013963)	
Filed	: June 8, 2006	Examiner: Nicoletta Kennedy
For	: A SOLID ORAL TOOTH WHITENING CONFECTIONARY COMPOSITION	

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, **Mail Stop Appeal Brief-Patents**
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir :

This appeal is under 35 U.S.C. 134 from the decision of the Examiner finally rejecting claims 1, 3-15 and 22-29 as forth in the Final Office Action dated June 3, 2010 as modified by the Advisory Action dated August 3, 2010.

A Notice of Appeal to the June 3, 2010 Final Office Action has been filed on October 4, 2010 so that the time for filing an Appeal Brief extends until December 4, 2010.

Appellant notes that this Appeal Brief is being filed within two months from the filing of the Notice of Appeal so that an extension of time and the government fee associated therewith should not be necessary for maintaining the pendency of the application. However, if any extension of time and/or any fee is necessary for maintaining the pendency of the application, including any extension of time and/or any appeal fee, this is an express request for any required extension of time and authorization to charge any necessary fee to Deposit Account No. 19-0089.

The requisite fee under 37 C.F.R. 41.20(b)(2) in the amount of $540.00 for the filing of the Appeal Brief is being paid herewith.

As noted above, if for any reason any extension of time and/or any fee is required to maintain the pendency of the application, including any extension of time and/or appeal fee, authorization is hereby provided to charge any required fee, including any fee for the Appeal Brief and any necessary extension of time fee to Deposit Account No. 19-0089.

(I) REAL PARTY IN INTEREST

The real party in interest is CADBURY HOLDINGS LIMITED by an assignment recorded October 3, 2008, at 021631, Frame 0405.

(II) RELATED APPEALS AND INTERFERENCES

None

There are no pending related appeals and/or interferences.

(III) STATUS OF CLAIMS

The status of the claims is as follows:

Claim 2 is canceled, and claims 1 and 3-29 are pending in this application. Of the pending claims, claims 16-21 stand withdrawn from consideration by the Examiner as being drawing to a non-elected invention, and claims 1, 3-15 and 22-29 are under appeal.

Of the pending claims, claims 1, 3-15 and 22-29 have been finally rejected in the Final Office Action, dated June 3, 2010, with the rejection being modified in the Advisory Action, dated August 3, 2010, so as to include the claims as amended in the Amendment to the Final Office Action, filed July 19, 2010, and are under appeal.

(IV) STATUS OF AMENDMENTS

The appeal is based upon finally rejected claims. An Amendment to the Final Office Action dated June 3, 2010, was filed July 19, 2010. An Advisory Action, dated August 3, 2010, indicated that for purposes of appeal the amendment filed July 19, 2010 would be entered and claims 1, 3-15 and 22-29 are rejected, and claims 16-22 are withdrawn from consideration.

A telephone interview was conducted on August 19, 2010, an Examiner Interview Summary was mailed on August 25, 2010, and a Statement of Interview was filed by Appellant on October 4, 2010.

(V) SUMMARY OF THE CLAIMED SUBJECT MATTER

The following description is made with respect to the independent claim and includes references to particular parts of the specification. As such, the following is merely exemplary and is not a surrender of other aspects of the present invention that are also enabled by the present specification and that are directed to equivalent compositions within the scope of the claims.

Independent claim 1 recites a tooth whitening lozenge composition comprising a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials (e.g., page 3, lines 3-5; page 4, lines 26-28), said composition comprising:

a) a water-soluble lozenge base (e.g., Example 1, page 10, lines 9-28p page 13, beginning at line 22),

b) lozenge additives (e.g., page 5, line 16 to page 6, line 9), and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition (e.g., page 4, lines 8-11).

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(a) Claims 1, 3, 4, 6-9, 11-13 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over abstract, WO 97/19668 to Tame-Said (hereinafter Tame-Said) in view of U.S. Patent No. 3,928,618 to Bauman (hereinafter "Bauman").

(b) Claims 11, 14, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of U.S. Patent No. 6,682,722 to Majeti et al. (hereinafter "Majeti").

(c) Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of U.S. Patent No. 6,685, 912 to Holme et al. (hereinafter "Holme").

(VII) ARGUMENT

(I) Traversal of rejection of claims 1, 3, 4, 6-9, 11-13 and 22-25 as rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman.

(a) Claims 1, 3, 4, 6-9, 11-13 and 22-25 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman.

(A) Arguments for Independent Claim 1 and Dependent Claims 4, 6, 8 and 11-13

The rejection of independent claim 1 and dependent claims 4, 6, 8 and 11-13 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject these claims should be reversed, and the application should be remanded to the Examiner.

Appellant's independent claim 1 is directed to a tooth whitening lozenge composition comprising a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a water-soluble lozenge base,

b) lozenge additives, and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

Appellant submits that this ground of rejection is without appropriate basis, and should be withdrawn.

Appellant submits that Tame-Said in view of Bauman does not teach or suggest the subject matter recited in Appellant's claim 1.

Initially, Appellant notes that Tame-Said is in a foreign language, and only includes English in the form of an English abstract. The rejections of record only refer to the English

abstract in the statement of the rejection by referring to "abstract, WO 97/19668" in the statement of the rejections and only pointing out disclosure of Tame-Said present in the abstract.

Tame-Said discloses a toothpaste and mouthwash composition in tablet form which dissolves in the mouth. The express object of the composition of Tame-Said as stated in the abstract of Tame-Said is the prevention of periodontal diseases. By contrast, Appellant's claim 1 is directed to a tooth whitening lozenge composition comprising a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a water-soluble lozenge base,

b) lozenge additives, and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

Furthermore, Tame-Said discloses that each tablet comprises ascorbic acid, sodium bicarbonate tricalcium phosphate, sodium lauryl sulfate, arabic gum, natural sweeteners and flavouring agents. The abstract of Tame-Said is silent on the use of calcium pyrophosphate in the composition. Moreover, the abstract of Tame-Said is silent relating to tooth whitening.

The fact that tricalcium phosphate is a polishing agent as allegedly evidenced by Bauman is immaterial to the question of whether a skilled artisan would have desired any tooth whitening effect in the composition disclosed in Tame-Said. There is no teaching or suggestion of any desirability of tooth whitening in the composition of Tame-Said, and there is no reason shown in the prior art to modify Tame-Said to achieve tooth whitening.

Bauman relates to oral compositions consisting essentially of a non-ionic organic surfactant and a quaternary ammonium aryl ester (Bauman, column 1, lines 7-10). The

quaternary ammonium aryl ester is found to possess bacteriostatic effectiveness (Bauman, column 2, lines 3-36). The composition of Bauman thus exhibits anti-microbial, anti-caries and anti-calculus properties, as disclosed in the abstract of Bauman. Hence, Bauman also relates to an objective that is different from the tooth whitening of Appellant's claimed subject matter.

In addition, Bauman teaches, beginning at column 4, line 66, that the oral composition may be incorporated in a dentifrice, such as a dental cream, tablet or powder. As a vehicle, the dentifrice may contain 20-95% of a water-insoluble polishing material selected from a variety of possibilities including calcium pyrophosphate (Bauman, column 5, lines 3-4). The only example in Bauman containing water-insoluble phosphates relates to a dental cream (Bauman, Example 1, at column 6) containing 46.75% dicalcium phosphate dihydrate. Clearly and as acknowledged by Bauman, the application of dental cream typically involves the mechanical application by brushing the teeth thereby achieving abrasive effects (Bauman, column 6, lines 3-6).

Significantly, the remaining examples in Bauman relate to mouthwash not containing any polishing agent whatsoever (Bauman, column 6). In contrast to dental cream, mouthwash is not applied by mechanical brushing action.

Thus, one having ordinary skill in the art would not have combined the disclosures of Tame-Said and Bauman in the manner asserted in the rejection, especially when Tame-Said is directed to a toothpaste and mouthwash composition in tablet form which dissolves in the mouth, and Bauman does not disclose a polishing agent in his mouthwash examples.

According to the present invention, calcium pyrophosphate has been surprisingly found to exhibit improved stain removal when incorporated into a lozenge comprising a water-soluble lozenge base. Applicant's composition provides a composition that through a water-soluble lozenge achieves tooth-whitening effectiveness of calcium pyrophosphate without needing

mechanical application. It is surprising that such tooth-whitening effectiveness is not limited to mechanically applied (e.g., by brushing action) oral compositions such as dental creams, but is seen to a surprisingly high degree in a lozenge composition that merely dissolves in the oral cavity owing to the water-soluble lozenge base.

At best, one having ordinary skill in the art learns from Bauman that calcium pyrophosphate may be used as one of many possible polishing materials in dental cream. However, Bauman is silent on tooth whitening effects conferred on a lozenge or tablet composition, which is not applied mechanically, such effect being conferred by polishing materials in general and by calcium pyrophosphate in particular. To the contrary, one having ordinary skill in the art would understand from Bauman, in particular, from the examples therein, that in oral compositions not requiring mechanical brushing application the use of polishing agents can be dispensed with since no tooth whitening effect is expected in this regard. Bauman thus clearly teaches away from such a modification.

Bauman does disclose that, "Typically, the oral preparation is a dentifrice, such as a dental cream, tablet or powder, containing as a vehicle about 20-95% by weight of a water-insoluble polishing material, preferably including water-insoluble phosphate such as dicalcium phosphate, tricalcium phosphate, trimagnesium phosphate, calcium pyrophosphate, dimagnesium phosphate and calcium carbonate." Therefore, Bauman once again discloses, as shown in his examples, that a dentifrice such as a dental cream, tablet or powder can include a polishing agent. This disclosure is in accordance with Bauman's examples wherein a dentifrice, such as a dental cream, table or powder, can be formulated with a polishing agent in high amounts as disclosed by Bauman, i.e. about 20-95%, agent. However, this disclosure in no way teaches or suggests Appellant's recited tooth whitening lozenge composition with its recited ingredients

including a tooth whitening agent comprising calcium pyrophosphate present in an amount of between 0.1 and 10% by weight of the composition.

Thus, for at least this reason, one having ordinary skill in the art would not have been motivated to substitute calcium pyrophosphate for tricalcium phosphate in a tablet composition according to Tame-Said. One having ordinary skill in the art would not seek to improve the improve tooth-whitening properties of Tame-Said's tablet composition, especially when the abstract of Tame-Said is silent in this regard, and would not find any guidance in Bauman. **Moreover, the disclosure of Bauman would lead to the conclusion that polishing agents, such as calcium pyrophosphate, are to be dispensed with in oral compositions that are not applied mechanically.**

Moreover, claim 1 further defines the weight percentage of calcium pyrophosphate being 0.1 to 10% by weight of the composition. As acknowledged in the rejection, the abstract of Tame-Said teaches a weight percentage of 11.59% of tricalcium phosphate. As explained above, Appellant submits that a person having ordinary skill in the art would not have modified Tame-Said by substituting calcium pyrophosphate for tricalcium phosphate based on the teaching of Bauman. However, even if for the sake of argument the disclosures were combined, one having ordinary skill in the art would not have arrived at the claimed range of 0.1 to 10% by weight, especially when Bauman discloses about 20-95% by weight of the polishing agent which may be calcium pyrophosphate and Example 1 of Bauman includes such a high weight by including 5% by weight of calcium carbonate (precipitated) and 46.75% by weight dicalcium phosphate dehydrate. Certainly, there is no motivation to arrive at Appellant's recited 0.1 to 10% by weight of calcium pyrophosphate from the high concentrations of polishing agent in a dentifrice disclosed by Bauman.

Moreover, the rejection has dismissed Appellant's recited range as an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present situation, neither Tame-Said nor Bauman teaches that the use of calcium pyrophosphate would achieve a tooth whitening effect in an oral composition that is not applied mechanically such as a lozenge. In fact, neither Tame-Said nor Bauman discloses that the weight percentage of calcium pyrophosphate would be of any relevance in this regard.

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason following the prior art for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Still further, Bauman does not disclose polishing agents such as calcium pyrophosphate in oral compositions that are not applied mechanically (Examples 2 and 3 as contrasted to Example 1). Thus, the weight percentage of calcium pyrophosphate in a lozenge composition can hardly be considered a result-effective variable based upon the teachings of Tame-Said and Bauman.

Appellant therefore respectfully submits that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman.

Moreover, in the Advisory Action dated August 3, 2010, the Examiner contends that the motivation for substitution in prior art references does not need to match the motive of applicant for combination in the instant claims. The fact that such a combination would have been within the purview of one of ordinary skill in the art, irrespective of the reason for combination, is sufficient to establish a case of prima facie obviousness. However, for the reasons set forth above, the rejection is improperly relying upon hindsight improperly relying upon Appellant's disclosure and not motivation in the prior art to arrive at Appellant's claimed subject matter.

Dependent claims 4, 6, 8 and 11-13 are patentable at least for the reasons set forth with respect to independent claim 1.

Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(B) Arguments for Dependent Claim 3

The rejection of dependent claim 3 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 3 further patentably defines independent claim 1 by reciting that the calcium pyrophosphate is present in an amount of between 0.5% and 9% by weight of the composition. Therefore, claim 3 is patentable for at least the reasons set forth with respect to independent claim 1, and for the additional reasons set forth herein.

As explained above, Appellant submits that a person having ordinary skill in the art would not have modified Tame-Said by substituting calcium pyrophosphate for tricalcium

phosphate based on the teaching of Bauman. However, even if for the sake of argument the disclosures were combined, one having ordinary skill in the art would not have arrived at the claimed range of 0.5 to 9% by weight, especially when Bauman discloses about 20-95% by weight of the polishing agent which may be calcium pyrophosphate and Example 1 of Bauman includes such a high weight by including 5% by weight of calcium carbonate (precipitated) and 46.75% by weight dicalcium phosphate dehydrate. Certainly, there is no motivation to arrive at Appellant's recited 0.5 to 9% by weight of calcium pyrophosphate from the high concentrations of polishing agent in a dentifrice disclosed by Bauman.

Moreover, the rejection has dismissed Appellant's recited range as an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present situation, neither Tame-Said nor Bauman teaches that the use of calcium pyrophosphate would achieve a tooth whitening effect in an oral composition that is not applied mechanically such as a lozenge. In fact, neither Tame-Said nor Bauman discloses that the weight percentage of calcium pyrophosphate would be of any relevance in this regard.

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Still further, Bauman does not disclose polishing agents such as calcium pyrophosphate in oral compositions that are not applied mechanically (Examples 2 and 3 as contrasted to Example 1). Thus, the weight percentage of calcium pyrophosphate in a lozenge composition can hardly be considered a result-effective variable based upon the teachings of Tame-Said and Bauman.

Appellant therefore respectfully submits that the claimed range recited in dependent claim 3 is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(C) Arguments for Dependent Claim 7

The rejection of dependent claim 7 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 7 further patentably defines independent claim 1 by reciting through dependent claim 6 that the oral tooth whitening lozenge composition comprises at least one additional tooth whitening agent, and said at least one additional tooth whitening agent is present in between 0.01% and 5.0% by weight of the composition.

Therefore, claim 7 is patentable for at least the reasons set forth with respect to independent claim1 and dependent claim 6, and for the additional reasons set forth herein.

The rejection admits that Tame-Said discloses that sodium bicarbonate is present at

14.49% by weight in an attempt to establish obviousness of an additional tooth whitening agent being present between 0.01% and 5.0% by weight of the tablet of Tame-Said. The only support in the rejection for this assertion of obviousness is the assertion that Appellant's recited range is an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Appellant therefore respectfully submits that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(D) Arguments for Dependent Claim 9

The rejection of dependent claim 9 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 9 further patentably defines independent claim 1 by reciting through dependent claims 6 and 8 that the at least one additional tooth whitening agent comprises sodium bicarbonate, the agent being present in between 0.1% and 0.5% by weight of the composition. Therefore, claim 9 is patentable for at least the reasons set forth with respect to independent claims 1 and dependent claims 6 and 8, and for the additional reasons set forth herein.

The rejection admits that Tame-Said discloses that sodium bicarbonate is present at 14.49% by weight in an attempt to establish obviousness of an additional tooth whitening agent being present between 0.1% and 0.5% by weight of the tablet of Tame-Said. The only support in the rejection for this assertion of obviousness is the assertion that Appellant's recited range is an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Appellant therefore respectfully submits that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(E) Arguments for Dependent Claim 22

The rejection of dependent claim 22 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 22 further patentably defines independent claim 1 through claim 3 by reciting that the calcium pyrophosphate is present in an amount of between 1.0% and 6.5% by weight of the composition. Therefore, claim 22 is patentable for at least the reasons set forth with respect to independent claim 1and dependent claim 3, and for the additional reasons set forth herein.

As explained above, Appellant submits that a person having ordinary skill in the art would not have modified Tame-Said by substituting calcium pyrophosphate for tricalcium phosphate based on the teaching of Bauman. However, even if for the sake of argument the disclosures were combined, one having ordinary skill in the art would not have arrived at the claimed amount of between 1.0% and 6.5% by weight, especially when Bauman discloses about 20-95% by weight of the polishing agent which may be calcium pyrophosphate and Example 1 of Bauman includes such a high weight by including 5% by weight of calcium carbonate (precipitated) and 46.75% by weight dicalcium phosphate dehydrate. Certainly, there is no

motivation to arrive at Appellant's recited amount of between 1.0% and 6.5% by weight of calcium pyrophosphate from the high concentrations of polishing agent in a dentifrice disclosed by Bauman.

Moreover, the rejection has dismissed Appellant's recited range as an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present situation, neither Tame-Said nor Bauman teaches that the use of calcium pyrophosphate would achieve a tooth whitening effect in an oral composition that is not applied mechanically such as a lozenge. In fact, neither Tame-Said nor Bauman discloses that the weight percentage of calcium pyrophosphate would be of any relevance in this regard.

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Still further, Bauman does not disclose polishing agents such as calcium pyrophosphate in oral compositions that are not applied mechanically (Examples 2 and 3 as contrasted to Example 1). Thus, the weight percentage of calcium pyrophosphate in a lozenge composition can

hardly be considered a result-effective variable based upon the teachings of Tame-Said and Bauman.

Appellant therefore respectfully submits that the claimed range recited in dependent claim 22 is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(F) Arguments for Dependent Claim 23

The rejection of dependent claim 23 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 23 further patentably defines independent claim 1 through dependent claim 3 by reciting that the calcium pyrophosphate is present in an amount of between 1.5% and 4.0% by weight of the composition. Therefore, claim 23 is patentable for at least the reasons set forth with respect to independent claim 1 and dependent claim 3, and for the additional reasons set forth herein.

As explained above, Appellant submits that a person having ordinary skill in the art would not have modified Tame-Said by substituting calcium pyrophosphate for tricalcium phosphate based on the teaching of Bauman. However, even if for the sake of argument the disclosures were combined, one having ordinary skill in the art would not have arrived at the claimed amount of between 1.5% and 4.0% by weight, especially when Bauman discloses about 20-95% by weight of the polishing agent which may be calcium pyrophosphate and Example 1 of Bauman includes such a high weight by including 5% by weight of calcium carbonate (precipitated) and 46.75% by weight dicalcium phosphate dehydrate. Certainly, there is no

motivation to arrive at Appellant's recited amount of between 1.5% and 4.0% by weight of calcium pyrophosphate from the high concentrations of polishing agent in a dentifrice disclosed by Bauman.

Moreover, the rejection has dismissed Appellant's recited range as an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present situation, neither Tame-Said nor Bauman teaches that the use of calcium pyrophosphate would achieve a tooth whitening effect in an oral composition that is not applied mechanically such as a lozenge. In fact, neither Tame-Said nor Bauman discloses that the weight percentage of calcium pyrophosphate would be of any relevance in this regard.

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Still further, Bauman does not disclose polishing agents such as calcium pyrophosphate in oral compositions that are not applied mechanically (Examples 2 and 3 as contrasted to Example 1). Thus, the weight percentage of calcium pyrophosphate in a lozenge composition can

hardly be considered a result-effective variable based upon the teachings of Tame-Said and Bauman.

Appellant therefore respectfully submit that the claimed range recited in dependent claim 23 is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(G) Arguments for Dependent Claim 24

The rejection of dependent claim 24 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Appellant's dependent claim 24 further patentably defines independent claim 1 by reciting through dependent claims 6 and 7 that the at least one additional tooth whitening agent is present in between 0.05 and 1.0% by weight of the composition.

Therefore, claim 24 is patentable for at least the reasons set forth with respect to independent claims 1 and dependent claims 6 and 7, and for the additional reasons set forth herein.

The rejection admits that Tame-Said discloses that sodium bicarbonate is present at 14.49% by weight in an attempt to establish obviousness of an additional tooth whitening agent being present between 0.05 and 1.0% by weight of the tablet of Tame-Said. The only support in the rejection for this assertion of obviousness is the assertion that Appellant's recited range is an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-

95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Appellant therefore respectfully submits that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(H) Arguments for Dependent Claim 25

The rejection of dependent claim 25 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be reman5ed to the Examiner.

Appellant's dependent claim 25 further patentably defines independent claim 1 by reciting through dependent claims 6 and 7 that the at least one additional tooth whitening agent is present in between 0.1% and 0.5% by weight of the composition.

Therefore, claim 25 is patentable for at least the reasons set forth with respect to independent claims 1 and dependent claims 6 and 7, and for the additional reasons set forth herein.

The rejection admits that Tame-Said discloses that sodium bicarbonate is present at 14.49% by weight in an attempt to establish obviousness of an additional tooth whitening agent

being present between 0.1% and 0.5% by weight of the tablet of Tame-Said. The only support in the rejection for this assertion of obviousness is the assertion that Appellant's recited range is an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5, line 5; 5% + 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

The rejection also contends that, "Claiming lesser amounts of the polishing and whitening agents are required is not inventive." However, the rejection improperly does not establish any reason for including Appellant's claimed lesser amounts in the tablet of Tame-Said.

Appellant therefore respectfully submits that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman. Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(II) Traversal of rejection of claims 5, 10 and 15 as rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of Holme.

(a) Claims 5, 10 and 15 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of Holme.

(A) Arguments for Dependent Claims 5, 10 and 15

The rejection of dependent claims 5, 10 and 15 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of Holme is in error, the decision of the Examiner to reject these claims should be reversed, and the application should be remanded to the Examiner.

Dependent claims 5, 10 and 15 are patentable at least for the reasons forth with respect to independent claim 1.

Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

(III) Traversal of rejection of claims 11, 14, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of Majeti.

(a) Claims 11, 14, and 26-29 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman, and further in view of Majeti.

***(A) Arguments for Dependent Claims* 11, 14, and 26-29**

The rejection of dependent claims 11, 14 and 26-29 under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman and further in view of Majeti is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

Dependent claims 11, 14 and 26-29 are directly or indirectly dependent upon independent claim 1 and are patentable at least for the reasons set forth herein with respect to the rejection of claim 1. Moreover, these dependent claims each recite the presence of urea which is disclosed in Appellant's specification, at page 7, lines 14 and 15, as a plaque acid buffer. In contrast, the rejection contends that Majeti discloses urea peroxide as a bleaching agent. There is no teaching or suggestion in the documents used in the rejection of the inclusion of urea in a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials as recited in Appellant's claims.

Accordingly, this rejection is without sufficient basis in relying upon a bleaching agent of urea peroxide in the prior art, and does not establish the obviousness of Applicants' recited subject matter including urea let alone urea in the concentrations recited in Appellant's claims.

Accordingly, the rejection of record is without appropriate basis and should be withdrawn.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness, which is a prerequisite for maintaining a rejection under 35 U.S.C. 103(a). The Board is, therefore, respectfully requested to reverse the Final Rejection, and to allow the application to issue in its present form.

Respectfully submitted,
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Attachments: (VIII) Claims Appendix
(IX) Evidence Appendix
(X) Related Proceedings Appendix

(VIII) CLAIMS APPENDIX

CLAIMS ON APPEAL

1. A solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a water-soluble lozenge base,

b) lozenge additives, and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

3. The composition according to claim 1 wherein said calcium pyrophosphate is present in an amount of between 0.5% and 9% by weight of the composition.

4. The composition according to claim 1 wherein said lozenge additives comprise at least one of the following: sweeteners, high intensity sweeteners, taste enhancers, flavoring agents, coloring agents.

5. The composition according to claim 1 wherein said composition is sugar-free.

6. The composition according to claim 1 comprising at least one additional tooth whitening agent.

7. The composition according to claim 6 wherein said at least one additional tooth whitening agent is present in between 0.01% and 5.0% by weight of the composition.

8. The composition according to claim 6 wherein said at least one additional tooth whitening agent comprises a bicarbonate salt.

9. The composition according to claim 8 wherein said at least one additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.1% and 0.5% by weight of the composition.

10. The composition according to claim 1 wherein at least one of said additives and said tooth whitening agent is encapsulated.

11. The composition according to claim 1 further comprising at least one of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitizing agents, therapeutically active agents, and remineralizing agents.

12. The composition according to claim 1 further comprising a supplement.

13. The composition according to claim 12 wherein said supplement comprises vitamin C.

14. The composition according to claim 11 wherein said composition further comprises an oral hygiene promoting agent, and the oral hygiene promoting agent comprises urea, said urea being present in between 0.1% and 25% by weight of the composition.

15. The composition according to claim 1 in the form of hard-boiled lozenges.

22. The composition according to claim 3 wherein said calcium pyrophosphate is present in an amount of between 1.0 % and 6.5 % by weight of the composition.

23. The composition according to claim 3 wherein said calcium pyrophosphate is present in an amount of between 1.5 % and 4.0 % by weight of the composition.

24. The composition according to claim 7 wherein said at least one additional tooth whitening agent is present in between 0.05 and 1.0% by weight of the composition.

25. The composition according to claim 7 wherein said at least one additional tooth whitening agent is present in between 0.1% and 0.5% by weight of the composition.

26. The composition according to claim 11 wherein said composition further comprises an oral hygiene promoting agent, and the oral hygiene promoting agent comprises urea, said urea being present in between 0.4% and 10% by weight of the composition.

27. The composition according to claim 11 wherein said composition further comprises an oral hygiene promoting agent, and the oral hygiene promoting agent comprises urea, said urea being present in between 0.6% and 5.0% by weight of the composition.

28. The composition according to claim 11 wherein said composition further comprises an oral hygiene promoting agent, and the oral hygiene promoting agent comprises urea, said urea being present in between 0.7 % and 3.5% by weight of the composition.

29. The composition according to claim 11 wherein said composition further comprises an oral hygiene promoting agent, and the oral hygiene promoting agent comprises urea, said urea being present in between 0.8 % and 2.5% by weight of the composition.

(IX) Evidence Appendix

Copies of evidence entered by the Examiner and relied upon by Appellant in the appeal along with statements setting from where in the record that evidence was entered in the record by the Examiner.

(a) Abstract, WO 97/19668 to Tame-Said - entered in the record in Form PTO-892 attached to Final Office Action mailed June 3, 2010.

(b) U.S. Patent No. 3,928,618 to Bauman – entered in the record in Form PTO-892 attached to the Office Action mailed December 7, 2009.

(c) U.S. Patent No. 6,685,916 to Holme et al. – entered in the record in Form PTO-892 attached to the Office Action mailed December 7, 2009.

(X) Related Proceedings Appendix

None